No. 10-972

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IN THE

Supreme Court of the United States

ELI LILLY AND COMPANY,

Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, LTD.,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF AMICUS CURIAE BIOTECHNOLOGY INDUSTRY ORGANIZATION IN SUPPORT OF PETITION FOR A WRIT OF CERTIORARI

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INTEREST OF *AMICUS CURIAE*[1]

Biotechnology Industry Organization ("BIO") is a trade association of over 1,150 corporate, academic, and non-profit members who research, develop, and produce innovative healthcare, agricultural, industrial and environmental biotechnology products. Due to the significance of the decision of the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") to BIO's members, and to the biotechnology industry as a whole, BIO submits its *amicus curiae* brief in support of Eli Lilly and Company's ("Lilly") Petition for a Writ of Certiorari (the "Petition").

BIO's members, including Lilly, invest heavily in research and product development to bring to market new products and therapeutic approaches that address major unmet health care needs such as cancer. BIO's members routinely engage in continuing research on basic biotechnology inventions even after initial patent applications have been filed. Often, such research reveals something new about a basic invention, including better and unexpected new ways of using it that require patent protection for their commercial development. Thus, BIO and its members have a continuing interest in ensuring that the Federal Circuit correctly and consistently applies the test for the judicially-created doctrine of nonstatutory double

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[1] No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amicus curiae*, or their counsel, made a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief. The parties have been given at least 10 days notice of the intention to file this *amicus* brief.

patenting. In particular, BIO and its members have an interest in ensuring that they can acquire patent protection for new inventions.

BIO submits its *amicus* brief based on its experience with the relevant laws. Pursuant to this Court's Rules, *amicus* briefs are appropriate when the party submitting the brief "brings to the attention of the Court relevant matter not already brought to its attention by the parties." SUP. CT. R. 37. BIO appears as *amicus* out of concern that the Federal Circuit has departed from its own clear precedent by expanding the judicially-created doctrine of nonstatutory double patenting in ways that negatively affect the patentability of important later-discovered uses and conflict with long-standing, express provisions of U.S. patent law. These matters are clearly "relevant" and will assist the Court in concluding that granting Lilly's Petition is appropriate. BIO's brief provides, *inter alia*, relevant Federal Circuit precedent and raises relevant matter not raised by the parties and should therefore aid the Court in its consideration of Lilly's Petition.

SUMMARY OF ARGUMENT

The Court should review and reverse the Federal Circuit's ruling that Lilly's U.S. Patent No. 5,464,826 (the "'826 patent" or "anticancer patent") is invalid in view of Lilly's U.S. Patent No. 4,808,614 (the "'614 patent" or "antiviral compound patent")(the "Opinion") under any patent statute or the U.S. Constitution. In exceeding even the judicially-created doctrine of nonstatutory double patenting and long-standing case law that double patenting concerns only claims, the Opinion raises important constitutional concerns regarding the patentability of inventions under 35 U.S.C. §101 and conflicts with longstanding and recent Federal Circuit precedent. The U.S. Supreme Court has not addressed the doctrine of non-statutory double patenting. This is a case that deserves its attention in finally providing the proper guidance as to its proper application.

The Federal Circuit has deprived Lilly of patent protection for a drug that it found useful for treating cancer by reaching into a specification of an unrelated application that was not even prior art or the statutorily correct specification to find that this specification invalidated the later-discovered and later-filed claims to treatment of cancer.

The Federal Circuit did not rely on any prior art under the patent statute's 35 U.S.C. § 102 on which to invalidate the claims of the anticancer patent; instead, it turned to nonstatutory double patenting. However, such a double patenting doctrine should not be applied to the instant case for two reasons. First, in determining whether later granted claims are obvious variants of earlier granted claims under a nonstatutory double patenting analysis, it is critical for a court to analyze the relevant sets of claims. Instead, the Federal Circuit relied on an unrelated specification as if the specification were prior art that operates only against the patentee. Second, even if under certain limited circumstances it is appropriate to look beyond the claims and consult the inventor's disclosure, the Federal Circuit used the

antiviral patent to invalidate the later-filed anticancer patent based on the antiviral patent's specification. The Federal Circuit did not follow the clear mandates of the patent statute, depriving Lilly of a patent for its invention under the U.S. Constitution and 35 U.S.C. § 101.

Double patenting has always focused on the claims, and it has long been the law that courts cannot use the earlier patent's specification in determining whether a later set of claims should be held invalid as simply an obvious variation of an earlier set of claims. *E.g., Gen. Foods Corp. v. Studiengesellschaft Kohle mbH*, 972 F.2d 1272 (Fed. Cir. 1992). In *Geneva Pharm., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003), the Federal Circuit created a limited exception to the general rule that the earlier patent's specification must be excluded from consideration. The Federal Circuit accessed an earlier patent's specification in the special situation where the utility of a claimed compound was not disclosed in the claims of the earlier patent but needed to be ascertained in order to determine whether a later claimed method of using the compound was patentably distinct.

The factual predicate that permits a *Geneva*-type analysis does not exist here. In the instant case, the utility of Lilly's antiviral compounds is apparent on the face of the earlier patent's claims. Accordingly, the Federal Circuit had no legal basis to turn to the specification and then use it, as if it were prior art, to invalidate later issued claims. Indeed, to access the specification in such a way would have been impermissible under long-standing precedent.

In addition, unlike the instant case, *Geneva* concerned a claimed compound that had a single utility that was disclosed in the earlier-filed patent claiming the compound; hence, the disclosed utility was the utility of a single invention. Here, in the patents at issue, Lilly first disclosed and claimed antiviral activity, thus the first invention. Lilly later discovered and claimed in an unrelated patent the anticancer

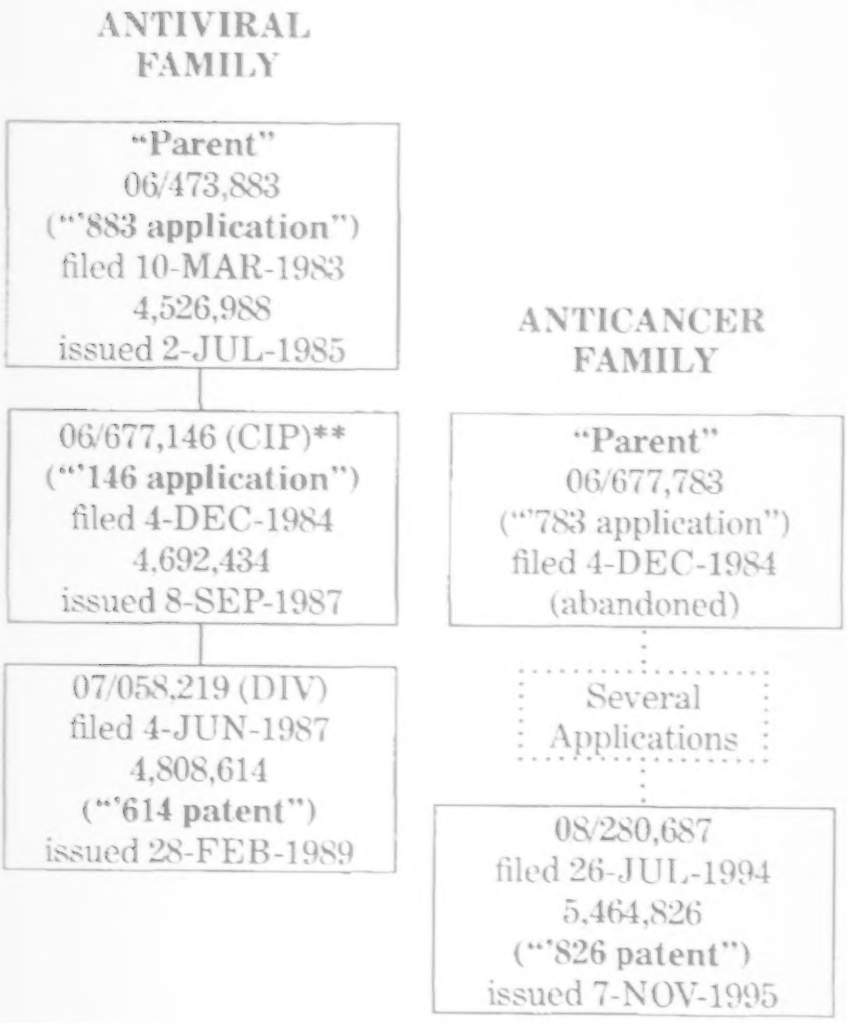
utility of the same compound. Lilly should not be deprived of its right to a patent for its new anticancer invention based on the Federal Circuit's impermissible departure from the patent statute and the doctrine of nonstatutory double patenting.

Lilly's petition for rehearing or hearing *en banc* was denied by five Federal Circuit judges. The four dissenting judges raised substantial concerns that the innovation community will no longer be able to obtain patent protection to which they are constitutionally entitled, 625 F.3d 719, 723 (Fed. Cir. 2010). Because the Federal Circuit failed to apply the governing statutes and its own precedent, the Court should, in consideration of the relevant case law outlined in BIO's brief, grant Lilly's Petition.

For the Court's convenience, a diagram of the relationships among Lilly's patents and the patent applications ("Two Unrelated Patent Families") is shown in Figure 1 as follows:

FIGURE 1

Lilly's Two Unrelated Patent Families for U.S. Patent Nos. 4,808,614 and 5,464,826*



* Each box stands for a patent application and shows the patent that the U.S. Patent and Trademark Office (USPTO) granted based on the application. The short-hand references to specific patent applications and patents that are relevant to this case are in bold.

** Lilly added mention of the anticancer activity to this '146 application, which the USPTO issued as the '434 patent, which did not claim any anticancer activity.

ARGUMENT

I. THE OPINION PROVIDES NO JUSTIFICATION FOR THE USE OF THE SPECIFICATION AS PRIOR ART FOR A NONSTATUTORY DOUBLE PATENTING ANALYSIS

As shown in the foregoing Figure 1, this case concerns two unrelated patent families: 1) one claiming compounds with antiviral activity ("antiviral family") and 2) the other claiming compounds with anticancer activity ("anticancer family"). The so-called "parent" of the antiviral family is Application Number 06/473,883, filed on March 10, 1983 (the "'883 patent application"). Lilly thereafter discovered the compounds' anticancer activity and on December 4, 1984, filed a separate, unrelated patent application, Application Number 06/677,783, to disclose and claim the compounds' anticancer activity. This new application ultimately led to the issuance of the '826 patent, which includes claims directed to a method of treating cancer.

On the same day, December 4, 1984, Lilly added new information on the claimed compounds' anticancer activity to a patent application in the antiviral family.[2] (*See* Figure 1.) The CIP application issued as U.S. Patent No. 4,692,434 (the "'434 patent") and did not claim any anticancer properties. A divisional application based on the CIP application was then filed on June 4, 1987, and issued as the '614 patent, also without any claims directed to cancer treatment.

Long-standing precedent of the Federal Circuit and its predecessor generally prohibits the use of a patent specification to support a holding of nonstatutory double

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[2] The new matter added to the application in the antiviral patent family made it a "continuation-in-part" ("CIP") application. 35 U.S.C. § 120.

patenting because a comparison of the claims is the *sine qua non* of such an analysis. *See, e.g., Gen. Foods*, 972 F.2d at 1277 ("Double patenting is altogether a matter of what is claimed"). In particular, the law of the Federal Circuit is that a patent's disclosure shall not be used "in support of a double patenting rejection...as though it were prior art...." *Id.* at 1281, *citing In re Braat*, 937 F.2d 589, 594 (Fed. Cir. 1991) ("patent disclosure must not be used as prior art"); *In re Vogel*, 422 F.2d 438, 442 (C.C.P.A. 1970) (same). This Federal Circuit precedent is consistent with the U.S. Supreme Court's statement of more than a century ago that claims of a second patent may be valid where a second patent covers matter described in a prior patent that is distinct and separable from the invention covered and claimed by the prior patent. *Miller v. Eagle Manufacturing Co.*, 151 U.S. 186, 198-199 (1894) (citation omitted).

In *Geneva*, the Federal Circuit acknowledged that *General Foods* constitutes the standard: "Because nonstatutory double patenting compares earlier and later claims, an earlier patent's disclosure is not available to show nonstatutory double patenting." *Geneva*, 349 F.3d at 1385. In view of the specific claims being compared, however, the *Geneva* Court recognized that a court may need to rely on the specification of an earlier issued patent to determine the utility of a claimed compound. There, the earlier issued Fleming patent contained a single claim to a compound described only by its chemical structure and a physical property. *Id.* The Fleming patent contained no other claims by which utility could be ascertained, such as a claim to a method of use. The Court therefore turned to the specification to understand the utility of the claimed compound. *Id.*

Similarly, in *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008), the earlier issued '165 patent contained only claims covering pharmaceutical compositions comprising certain compounds. No claim was directed to, or otherwise recited, a method of using the compounds. Relying on *Geneva*, the *Pfizer* Court turned to the

specification for the disclosure of the antiinflammatory utility of the claimed compounds in determining that the later issued '068 patent claiming methods of treating inflammation and associated disorders with the earlier claimed compounds was invalid for nonstatutory double patenting.

The *Geneva* and *Pfizer* cases require specific predicate facts – earlier patent claims directed solely to compounds without any indication of their utility – to warrant their application. In contrast to the *Geneva* and *Pfizer* factual predicate, Lilly's '614 antiviral patent does not contain compound claims "standing alone,"[3] as in *Geneva*, 349 F.3d at 1385, but rather contains compound, method of use, and pharmaceutical composition claims. *Sun Pharm. Indus., Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010). For example, claim 13 of the '614 patent claims a method of treating Herpes viral infections using the claimed compounds. *Sun*, 611 F.3d.at 1383. Similarly, claim 14 claims a pharmaceutical composition useful for treating Herpes viral infections. *Id.* To understand what is claimed for double patenting purposes, all of the claims must be considered. *See, e.g., Gen. Foods*, 972 F.2d at 1283; *see also In re Braat*, 937 F.2d at 593-594. The claims of the '614 antiviral patent, considered as a whole, clearly recite the claimed compounds' antiviral utility.

Because the '614 antiviral patent claims recite (and therefore disclose) a utility for the claimed compounds, the Federal Circuit had no basis, as in *Geneva* or *Pfizer*, to turn to the specification of the '614 patent. Rather, the Federal Circuit should have analyzed the claims of Lilly's patents for nonstatutory double patenting under the *General Foods* line

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[3] The Federal Circuit erroneously found otherwise. *Sun*, 611 F.3d at 1387-1388.

of cases,[4] and compared the '614 antiviral and '826 anticancer patent claims without reference to the specification of the earlier-issued antiviral patent. In failing to follow its own precedent, the Federal Circuit appears to have adopted a new standard allowing courts to freely compare later issued claims to the specification of an earlier issued patent, even if it includes new subject matter as in the instant case, thereby creating a conflict with decades of nonstatutory double patenting jurisprudence. To avoid further erosion of the long-standing *General Foods* precedent or, in the alternative, conflation of the *General Foods* and *Geneva* lines of cases, the Court should grant Lilly's Petition to clarify the law and provide clear guidance as to the proper application of *General Foods* and *Geneva*.

II. THE OPINION CONFLICTS WITH THE PATENT STATUTE § 120

As explained above, the Federal Circuit had no need or basis to consult the specification of Lilly's '614 antiviral patent to ascertain the utility of the claimed compounds.

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[4] The Federal Circuit justified its departure from the rule in *General Foods* by stating that "a court considering a claim to a compound must examine the patent's specification to ascertain the coverage of the claim, because a claim to a compound, 'standing alone . . . does not adequately disclose the patentable bounds of the invention.'" *Sun*, 611 F.3d at 1387. The Federal Circuit cites *Geneva* for this broad proposition. But this justification does not withstand serious scrutiny, especially if taken out of *Geneva's* specific context. Not all compound claims, "standing alone," fail to adequately define their "patentable bounds," and the Federal Circuit nowhere explains why or how the scope of the instant claims was deemed unclear, particularly in view of claims to methods of use.

However, even if the Federal Circuit were justified in consulting a specification for disclosure of the compounds' utility, the Federal Circuit consulted the wrong specification: the Federal Circuit consulted the specification that issued with new subject matter, not the specification as originally filed. In doing so, the Federal Circuit ignored the express provisions of the patent statute.

Section 120 of the patent statute accords patent applicants, like Lilly, the benefit of an earlier-filed application date, so long as the earlier-filed application provides sufficient support under 35 U.S.C. § 112 ¶ 1. *See* 35 U.S.C. § 120; *Trading Techs. Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340, 1359-60 (Fed. Cir. 2010). The parties do not dispute that, under Section 120, the '614 antiviral patent claims are entitled to the benefit of the date of the parent application, i.e., the earliest-filed patent application, its "parent," the '883 antiviral patent application, which disclosed only the claimed compounds' antiviral activity. (*See* Figure 1.) In December 1984, almost two years after the '883 patent application was filed, Lilly's scientists first disclosed but did not claim the anticancer activity of the '614 antiviral patent's compounds in the CIP application resulting in the '434 antiviral patent. Indeed, the fact that the PTO issued the '614 patent's claim 13, drawn to a method of treating Herpes viral infections, creates a presumption that the original antiviral activity of the compounds constitutes sufficient utility. Thus, Lilly should be accorded the full benefit of the original '883 antiviral patent application's disclosure for all purposes relevant here.

Contrary to long-standing precedent relating to Section 120, the Federal Circuit failed to accord Lilly the benefit of the March 1983 filing date of the parent '883 antiviral patent application to the '614 antiviral patent, which contained claims to antiviral activity but none to anticancer activity. (*See* Figure 1.) In consulting the specification of the issued '614 patent, the Federal Circuit gave no regard to the different dates of the antiviral and anticancer inventions and

treated the later anticancer invention as if it were present in the '883 parent patent application. In effect, the Federal Circuit has rendered unpatentable a new use that was discovered after the priority date of the earlier patent.

The Opinion's dependence on the later-disclosed anticancer activity also fails to stand up under the *Geneva* reasoning. In *Geneva*, the Federal Circuit justified looking to the utility disclosed in the earlier patent's disclosure by explaining that a compound patent could only be obtained by disclosing the compound's utility. *Geneva*, 349 F.3d at 1386. Accordingly, the utility disclosed for the claimed compound was deemed to be "an essential part of a single invention" and could not be deemed patentably distinct if later claimed in the form of a method. *Id.* The *Geneva* reasoning cannot apply to the instant case because the specification of the earlier patent in *Geneva* disclosed a single use for the claimed compound. Only under such circumstances was it appropriate to refer to the earlier patent's specification to determine the utility of claimed compounds as part of the "single invention." By consulting the specification of the '614 antiviral patent, however, the Federal Circuit ignored the facts in *Geneva* and considered the disclosure of the claimed compounds' anticancer utility as well as the compounds' antiviral utility disclosed in the patent's parent application. Lilly's later added anticancer disclosure could not be deemed "an essential part" of a single chemical invention and should therefore not be invoked against later issued claims under *Geneva*-type double patenting.

This Court should grant Lilly's Petition to provide clear guidance as to the proper application of *Geneva* and its interplay with Section 120.

III. BY CHANGING A RULE OF PATENTABILITY, THE OPINION CHANGES PUBLIC POLICY AND DISINCENTIVIZES NEW DISCOVERIES

BIO submits that courts should be particularly circumspect when expanding law that is not rooted in the statute. Any such expansion should be consistent with the statute as a whole and should be supported by a public policy rationale that creates proper incentives for continuing research and timely public disclosure. Biotechnology applicants are particularly likely to continue research on their basic biotechnology inventions and to discover new properties and activities about them, new modifications of them, and new uses for them.[5] Such patentees are now on notice that their patent specifications can be used for double patenting attacks without regard to whether, and when, new matter has been added, or the choice of application format. In the instant case, for example, the simple ministerial act of filing a continuation application would have allowed Lilly to claim the active ingredient in a patent with no disclosure of

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[5]For example, drug products which were developed for later-discovered uses include: sildenafil, changed from a candidate for hypertension to erectile dysfunction; finasteride, expanded from prostate cancer to hair loss; raloxifene, repositioned from birth control to osteoporosis; minoxidil, switched from a hypertension candidate to hair loss; thalidomide, changed from a discontinued antiemetic drug to a successful cancer therapeutic; hydroxychloroquine, expanded use from an antiparasitic to an approved antiarthritic agent; doxepin, expanded from an antidepressant to a antipruritic agent; naltrexone, expanded use from an opioid addiction therapeutic to alcohol withdrawal therapy; bimatoprost, expanded from glaucoma treatment to eyelid hypotrichosis.

its anticancer activity. The very simplicity with which double patenting could have thereby been avoided underscores how the Opinion elevates form over substance.

Notably, the Federal Circuit panel decision provides no policy rationale for its expansion from the holding in *Geneva*, and, indeed, furthers no public policy. Rather, it incentivizes applicants to minimize their application disclosures. Lilly suffers the detriment of expanding the disclosure of its patent specification with the results of its follow-on research and of erring on the side of disclosure. But the requirements of patentability, especially if not set forth in the statute but created by the courts, should incentivize desirable conduct, or at least should not punish innovators for engaging in desirable conduct that violated no rule at the time and that is wrong only in retrospect.

This Court has on more than one occasion cautioned against altering the patent law in a manner that risks "destroying the legitimate expectations of inventors in their property." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002). In *Festo*, for example, this Court noted that patent prosecution decisions are made based on case law as it is understood at the time and that any retrospective change can unfairly disrupt the settled expectations of the inventing community. *Id.* Not only do such changes undercut the incentive for future investment in innovation, but they "could very well subvert the various balances the PTO sought to strike when issuing the [patents]." *Id.*

It is critical that when patent law evolves in the courts, it does so in a way that does not disrupt the investment-backed expectations of the inventive community and does not punish patentees for decisions made during patent prosecution that were reasonably based on the law at that time. Not only is this unfair to settled expectations of inventors, but the biotechnology community needs to understand the ramifications of disclosure in patent specifications. Such

understanding will determine the timing in which applications are filed, the timing of research and disclosure thereof, and ultimately investment decisions that result in socially beneficial products. While the non-statutory, judicial doctrine of double patenting serves a useful purpose, it should be limited and not expanded to invalidate legitimate patent rights otherwise in full compliance with the patent statutes.

CONCLUSION

For the foregoing reasons, this Court should grant Lilly's petition for a writ of certiorari.

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